K093985
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NIPRO MEDICAL CORPORATION
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JAN 22 2010

510k Summary
NIPRO SafeTouch LockTail™ Safety Fistula Needle

807.92(a)(1)

Applicant:	Nipro Medical Corporation
Establishment Reg.:	1056186
Contact Person:	Jessica Oswald Regulatory Affairs Specialist
Date of summary preparation:	December 16, 2009

807.92(a)(2)

Trade Name: NIPRO SafeTouch LockTail™ Safety Fistula Needle
Common Name: Safety Fistula Needle
Classification Name: Blood access device and accessories
Regulation Number: 21 CFR 876.5540
Panel: 78
Product code: FIE

807.92(a)(3)

Legally marketed substantial equivalent device:
K032777 – NIPRO SafeTouch II Safety AVF Needle

807.92(a)(4)

Description of device:
The NIPRO SafeTouch LockTail™ Safety Fistula Needle is a sterile, single use, safety AVF needle. It consists of an arterial and venous adapter, flexible tube and needle with an active sharps safety feature (non-implanted blood access device) as described in 21 CFR 876.5540.

The NIPRO SafeTouch LockTail™ includes 2 basic types of designs; fixed wing type (stationary) and turnable wing type (rotating). These two designs are offered in 80 configurations with options that include needle gauge (14-18G), needle length (1" and 1 ¼"), type of needle (with or without backeye), clamp color (white, red/blue), and tubing length (150 and 300 mm).

The integrated sharps injury prevention feature requires physical action by the clinician to activate and is designed to cover the needle tip after treatment. Correct use of this anti-stick feature will eliminate accidental needlesticks.

These devices operate on the principles of a blood access device. They are sterile, single use only, non-toxic and non-pyrogenic.

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807.92(a)(5)

Indication for Use:

The Nipro SafeTouch LOCKTAIL™ is intended for use as a blood access device for blood purification and for other treatments requiring extracorporeal circuit. The Nipro SafeTouch LOCKTAIL ™ aids in the prevention of accidental needle stick injuries. The compatibility of available configurations is the responsibility of the physician in charge."

807.92(a)(6)

Comparison of technological characteristics:

The NIPRO SafeTouch LockTail™ Safety Fistula Needle is substantially equivalent to the predicate device in the following technological characteristics –

- Design
- Material
- Mechanical
- Physical characteristics
- Basic Scientific Technology
- Intended Use

807.92(b)(1)

Non-clinical tests submitted:

The results of biocompatibility data support the equivalence of the predicate device and include sterility, bacterial endotoxin, systemic injection, intracutaneous reactivity, hemolysis and implantation testing. Performance testing was also conducted and is included in this submission.

807.92 (b)(3)

Conclusions drawn from non-clinical and clinical tests:

The results of the performance testing and the comparison of technological characteristics with the predicate device demonstrate that the NIPRO SafeTouch LockTail™ Safety Fistula Needle performs equivalent to the predicate device and is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JAN 22 2010

Ms. Jessica Oswald
Regulatory Affairs Specialist
Nipro Medical Corporation
3150 NW 107th Ave
MIAMI FL 33172

Re: K093985
Trade/Device Name: NIPRO SafeTouch LockTail™ Safety Fistula Needle
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: FIE
Dated: December 21, 2009
Received: December 24, 2009

Dear Ms. Oswald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K093985

Indications for Use

510(k) Number: K093985

Device Name: NIPRO SafeTouch LOCKTAIL™ Safety Fistula Needle

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K093985